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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/080,504	02/22/2002	Olaf Reinhold	38466.00008.UTL	8672
36183	7590	09/21/2006	EXAMINER	
PAUL, HASTINGS, JANOFSKY & WALKER LLP P.O. BOX 919092 SAN DIEGO, CA 92191-9092			LEWIS, AARON J	
			ART UNIT	PAPER NUMBER
			3743	
DATE MAILED: 09/21/2006				

Please find below and/or attached an Office communication concerning this application or proceeding.

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Office Action Summary	Application No. 10/080,504	Applicant(s) REINHOLD ET AL.	
	Examiner AARON J. LEWIS	Art Unit 3743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 July 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-84 is/are pending in the application.
 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-84 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 1-19,21-42,43-61,63-84 are rejected under 35 U.S.C. 103(a) as being unpatentable over Voges ('841) in view of Stevens ('934).

As to claim 1, Voges discloses a device (fig.2) for delivering an aerosolized compound (e.g. nicotine at col.5, line 58), the device comprising: a reservoir (10) that stores the compound; a system comprising an entry port (12) and an element (14) to generate particles of a desired size for physical ejection through one or more apertures (15) from an ejection head (14) of the element, wherein said particles comprise a compound (e.g. nicotine at col.5, line 58), and wherein said system is fluidly connected (11) to a reservoir (10); and a housing (2,3) comprising an inlet (7) and an outlet (5) between which is formed an airflow path (see bold arrows in fig.2 extending from outside of housing 2,3 through inlet 7 and through outlet 5) and in which at least the ejection head is disposed in the air flow path (i.e. as illustrated in fig.2) downstream of the inlet (7) and upstream from the outlet (5), wherein the housing provides for a substantially unobstructed airflow between the ejection head and the outlet when air traverses the airflow path from the inlet to the outlet.

The difference between Voges and claim 1 is the inlet being directly behind the reservoir.

Stevens, in a device for delivering an aerosolized compound, teaches inlets (3 and 5) located directly "behind" (i.e. upstream of) a medicament reservoir (30,31). Stevens also teaches an inlet (5) located adjacent the medicament reservoir (30,31). Stevens discloses the advantages of having inlets adjacent to and directly "behind" (i.e. upstream of) a reservoir are to control the concentration of medicament being output from the device (page 1, line 92-page 2, line 26 and page 3, lines 82-113).

It would have been obvious to modify the housing of Voges to include an inlet directly "behind" (i.e. upstream of) the reservoir in addition to the existing inlets that are positioned adjacent the reservoir because it would have provided a means for controlling the concentration of medicament being output from the device as taught by Stevens.

As to claims 2 and 3, in Voges the compound (col.5, line 58) is a pharmaceutical compound and is stored in the reservoir (10) in a liquid formulation (col.5, line 58 discloses nicotine dissolved in water).

As to claims 4-7, Voges (col.9, line 53-col.10, line 21) discloses a variety of suitable drugs for delivery by the device. These drugs include proteins and hormones (e.g. corticosteroids and antidiuretic hormone), and small molecules (e.g. budesonide) as well as other drugs that are fully capable of being gene delivery vehicles.

As to claim 8, the reservoir (10) and particle generating system (14,15) in Voges (fig.2) are illustrated as being located within housing (2,3).

As to claim 9, the housing of Voges (fig.2) is aerodynamically shaped (e.g. cylindrically shaped thereby providing for easy flow of air therethrough and around).

As to claim 10, the reservoir (10) of Voges is disclosed as being detachable (col.6, lines 37-40).

As to claim 11, the reservoir (10) and particle generating system (11,12,14,15) of Voges is illustrated (e.g. in fig.2) as being integrated into a single unit.

As to claim 12, the particle generating system of Voges is an electronic ejection device (col.6, lines 45-51).

As to claim 13, Voges discloses the electronic ejection device uses heat (20 and col.6, lines 26-30) to generate particles ejected from the ejection head.

As to claim 14, Voges discloses the electronic ejection device includes a piezoelectric component (col.10, lines 52-54) to generate particles ejected from the ejection head.

As to claims 15-17, Voges discloses the desire particle size is one that allows particles to transit to and be deposited in alveoli (col.9, lines 37-47). That is, Voges recognizes that particles having a diameter less than 5 microns are preferred because particles of this size range will follow respiratory passages. One of ordinary skill would recognize respiratory passages to include alveoli.

As to claim 18, fig.2 of Voges illustrates substantially unobstructed airflow being substantially laminar prior to exiting the housing outlet (5).

As to claim 19, fig.2 of Voges illustrates substantially unobstructed airflow comprises a substantially homogeneous mixture of ejected compound and air from inlet (7) prior to exiting the housing outlet (5).

Claims 21-24 are substantially equivalent in scope to claims 1 and 18 and are included in Voges as modified by Stevens for the reasons set forth above with respect to claims 1 and 18.

Claims 25-42 are substantially equivalent in scope to claims 1-19 and are included in Voges as modified by Stevens for the reasons set forth above with respect to claims 1-19. Voges as discussed above also discloses a digitally controlled electronic ejection (col.6, lines 45-51) of aerosolized medicament.

The balance of the claims, 43-61,63-84, are substantially equivalent in scope to claims 1-19,21-42 and are included in Voges as modified by Stevens for the reasons set forth above with respect to claims 1-19,21-42.

3. Claims 20 and 62 are rejected under 35 U.S.C. 103(a) as being unpatentable over Voges ('841) in view of Stevens ('934) as applied to claims 1-19,21-42,43-61,63-84 above, and further in view of Gonzalez ('614).

The difference between Voges as modified by Stevens and claim 20 is an inner surface of the housing is proximal to the ejection head and extending to the outlet is contoured to minimize turbulence.

Gonzalez, in a device for delivering an aerosolized compound (page 1, col.2, lines 100+), teaches an inner surface of the housing is proximal to the aerosol generation system and extending to the outlet is contoured (A' to a2 to e2 of fig.1). The contouring

of the inner surface of the housing of Gonzalez would implicitly cause variations in the flow rate and flow pattern of the aerosol being formed as it passes therethrough (e.g. smaller diameter portions would cause increased flow rate and more laminar flow whereas increased diameter portions would cause decreased flow rate and relatively more turbulent flow.

It would have been obvious to further modify the inner surface of the housing of Voges proximal to the ejection head to make it contoured because it would have provided a means for controlling the flow rate and flow pattern of the aerosol being formed as taught by Gonzalez.

Claim 62 is substantially equivalent in scope to claim 20 and is included in Voges as further modified by Gonzalez for the reasons set forth above with respect to claim 20.

Response to Arguments

4. Applicant's arguments filed 07/03/2006 have been fully considered but they are not persuasive. In response to applicant's arguments against the references individually (i.e. Stevens for allegedly lacking a substantially unobstructed airflow and Gonzalez for allegedly lacking an unobstructed airflow path among other features that the base reference to Voges already discloses), one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Applicant's arguments regarding the positioning of inlets upstream of the reservoir (10) of Voges due to an alleged adverse effects on pressure sensor (19) are not

persuasive because there is no evidence to support such a conclusion. Voges specifically discloses the pressure sensor to be responsive to patient inhalation for timely triggering a dose of medicament; there is no mention of it being adversely affected by airflow from inlets.

Applicant's arguments that Voges teaches away from positioning inlets in wall (9) may be accurate; however, the combination of Voges and Stevens does not teach that inlets must be located in wall (9) of Voges; rather, the combination teaches inlets at a position that is upstream of the reservoir. In Voges the minimum upstream point would be at a point along the wall at reference numeral #3 which is not specifically in wall (9).

Conclusion

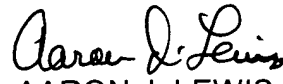
5. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to AARON J. LEWIS whose telephone number is (571) 272-4795. The examiner can normally be reached on 9:30AM-6:00PM M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, HENRY A. BENNETT can be reached on (571) 272-4791. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


AARON J. LEWIS
Primary Examiner
Art Unit 3743

Aaron J. Lewis
September 17, 2006